

FY 2022 CONGRESSIONAL HEARING FACT SHEET

SERESTO PET COLLAR INCIDENTS AND EPA's REGULATION OF PET PRODUCTS

BACKGROUND:

- Seresto is a dog and cat collar designed to kill fleas, ticks and lice and contains flumethrin and imidacloprid.
- It was first registered in 2012 with the company Bayer. It is now owned by Elanco.
- The collar is also used on Arizona tribal lands and has successfully reduced the number of Rocky Mountain Spotted Fever infections in local tribal communities.
- Since it was registered in 2012, there have been over 86,000 incidents reported on the collar.
- Seresto is registered in the EU but PMRA declined to register the collar during their review.
- Recently there have been numerous press inquiries on the Seresto pet incidents, in addition to congressional inquiries from the Subcommittee on Economic and Consumer Policy and Senator Bernard Sanders.

KEY POINTS:

- The Seresto incidents are required to be reported under the adverse effects provisions of FIFRA 6a2, to which all pesticide products are subject. When appropriate, additional information can be requested by the Agency under the authority of 6a2.
- The incidents range in severity from small rashes to pet death. Incidents are rated for plausibility from unlikely that the collar caused the incident to probable.
- The number of incidents alone make it difficult to understand if there is a serious issue with the collar. The incident numbers are not tied to U.S. sales, often provide minimal details, and are not compared to incidents received from other pet products. Further, these incidents are also based on observation of consumers. Clinical professionals may not be consulted.
- Generally, there is no process for verifying the information in reports. Many of the reports are anecdotal, with no indication of whether the user followed label use instructions or used a product appropriate for the pet type and size.
- OPP staff are working across the federal agency community to ensure the best analyses of these products are possible. This includes reaching out to experts within FDA's Center for Veterinary Medicine that regulate similar products under their jurisdiction.
- **Ex. 5 Deliberative Process (DP)**

 FDA's Center for Veterinary Medicine regulates most veterinary products in the U.S., and

Ex. 5 Deliberative Process (DP)

 has extensive pre-market review and post-market surveillance programs under the Federal Food, Drug, and Cosmetic Act.

TALKING POINTS:

- The safety of all pesticide products is of highest priority to the agency. We work every day to ensure that products in the marketplace are safe.
- The Agency is currently in discussions with Elanco to further understand the number of Seresto incidents.
- EPA encourages pet owners to discuss with their veterinarian whether flea and tick control is needed for their pets, which type of control product they should use if one is needed, to read the entire label before using the recommended pesticide product, and to follow all directions carefully, including monitoring the pet after application to see if side effects occur. If side effects develop, the label tells the consumer to consult the pet's veterinarian immediately.